

FOOD AND DRUG ADMINISTRATION
Center for Drug Evaluation and Research (CDER)
Arthritis Advisory Committee (AAC)
September 16, 2009

BLA 125338 Xiaflex (clostridial collagenase)

QUESTIONS FOR THE COMMITTEE

1. Investigator training in the clinical studies included injection technique instruction via manuals and DVDs, workshops, and investigator meetings. This may be more extensive than the training proposed for the education of healthcare professionals in clinical practice if the product is approved. Please discuss the adequacy of the proposed training.
2. VOTE: In view of the data available for safety and efficacy, do you recommend approval of Auxilium's clostridial collagenase for the treatment of patients with advanced Dupuytren's Disease?
3. Depending on your response to Question 2, please address the following questions:
 - a. If you recommend approval, what additional studies, if any, should be conducted post-approval to further assess the safety of the product?
 - b. If you do not recommend approval, what additional data are needed to support approval?